June 7, 2022

Submitted via email and regulations.gov

Maureen Gwinn, PhD
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Office of Research and Development (ORD)
U.S. Environmental Protection Agency
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Dear Dr. Gwinn,

I am writing in response to your June 2, 2022, letter denying the American Chemistry Council's (ACC) request for an extension of the public comment period on the draft IRIS Assessment of Formaldehyde. In that letter EPA denied ACC's request for a 60-day extension. Given the volume of material and the complexity of the issues, EPA's failure to provide an extension, even if not the full 60-days, constitutes another significant procedure failing and further undermines the scientific integrity of the IRIS assessment development process. Accordingly, we renew our request that the Agency extend the comment period.

While 60-days may be a typical time frame for comment, it is not statutorily mandated and the Agency often provides longer time where the issues are novel and/or complex, as it should have done here. For example, in 2010, EPA announced the availability of the last draft IRIS assessment of formaldehyde through the Federal Register ahead of review by the National Academies. At that time, the Agency provided a 90-day comment period along with a public listening session.[1] In the last year, EPA has also extended comment periods associated with the IRIS Assessment Plan for Vanadium[2] and the draft assessment for Perfluorobutanoic Acid (PFBA) and Related Compound Ammonium Perfluorobutanoic Acid.[3] Failure to provide adequate time for comment, or to fully consider those comments, can undermine and call in to question any regulatory action which might rely upon the finalized value.

We are similarly very concerned with deficiencies in the Agency's interagency review process. While your response letter refers to the review as a formal review, it is unclear if other federal agencies, including the U.S. Department of Agriculture, Department of Transportation, and Food and Drug Administration, were properly engaged or understood the potential implications for their agencies and

[1] 75 Fed. Reg. 30825 June 2, 2010.
[2] 86 Fed. Reg. 22704 June 25, 2021.
[3] 86 Fed. Reg. 58075 October 20, 2021

their regulated communities. Moreover, the time provided by EPA for comment was extremely short given the voluminous nature of the material and because the interagency review period included the period between Christmas and New Year's Day. Accordingly, we urge EPA to engage with these Agencies to ensure that any relevant information or concerns that they may have been addressed in the external peer review draft.

EPA's focus in developing an IRIS value should be a comprehensive evaluation of the scientific issues and an effort to ensure that the full body of scientific literature is thoroughly and impartially evaluated, which the Agency does not appear to be doing here. Indeed, the letter denying the request for an extension appears to have prejudged several significant issues that have been, or will likely be, raised in connection with this review—for example consistency with the prior direction from NASEM and the IRIS Handbook. Indeed, ACC has already raised a number of these important concerns with EPA (See attachments).

Moreover, in denying ACC's request, EPA has provided no explanation of how the additional time requested will fundamentally undermine the Agency's efforts to address its perceived concerns with the adequacy of current regulatory standards. This concern, of course, presupposes the correctness of the Agency's new value and it is difficult to understand how adding 60-days to allow for fuller public comment at this stage impedes the Agency's goals, especially given the amount of time it took the Agency to release the proposed value. While it may be the case that there will be additional opportunities for comment, the Agency should make sure that it has a complete record as early in the process as possible and that it has addressed the material prior to initiating the external peer review to ensure an efficient and scientifically robust process based on complete information.

Respectfully,

Elliott Zenick
Assistant General Counsel
On Behalf of the ACC Formaldehyde Panel

cc:

Christopher Frey, Assistant Administrator, Office of Research and Development (ORD)

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